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ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
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MEMORANDUM

April 30, 2017

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Examining Improvements to the Regulation of Medical Technologies"

On **Tuesday, May 2nd at 10:00 a.m. in Room 2123 of the Rayburn House Office Building**, the subcommittee will hold a hearing on additional legislation related to the review and regulation of medical devices.

I. OVER THE COUNTER HEARING AIDS

A. Background

It is estimated that 30 million people in the United States have hearing loss, and that number is expected to grow as the population ages.[1] Though age-related hearing loss is a common problem, only 15-30 percent of Americans use assistive hearing technologies.[2] Low-income individuals and ethnic minorities have an even lower adoption rate.[3]

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[1] Frank R. Lin et al, *Hearing Loss Prevalence in the United States,* Archives of Internal Medicine (Nov. 14, 2011) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3564588/).

[2] Letter from the Executive Office of the President, President's Council of Advisors on Science and Technology to the President (October 2015) (https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final.pdf).

[3] Kathleen E. Bainbridge and Virginia Ramachandran, *Hearing Aid Use among Older United States Adults: The National Health and Nutrition Examination Survey, 2005–2006 and 2009–2010,* Ear and Hearing (2014) (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3999213/).

While there are multiple factors affecting hearing aid adoption rates, it is generally agreed that the cost of obtaining hearing aids is one of the largest barriers to access. Recent surveys have found that the average price of one hearing aid is approximately $2400, with premium models costing up to $2900.[4] Because Medicare and most private insurance plans do not cover the cost of hearing aids or their fitting, most people are paying for their hearing aid entirely out of pocket. Hearing aid costs are typically encompassed in a single-price, bundled package. A hearing aid bundle usually includes a professional evaluation, the hearing-aid devices, and a follow-up appointment for adjustment of the device. Earlier analyses found that the devices account for less than half of the bundled price. Surveys also suggest that many people do not use all the services included in the bundle and that patients are locked into the services of a single professional.[5]

Over-the-counter (OTC) hearing aids, which would not require professional evaluation, present a lower-cost and more accessible option for those affected by age-related hearing loss.

Recently, an expert committee convened by the National Academies of Sciences, Engineering, and Medicine to study hearing health care in adults issued a report that made a number of recommendations as to how to improve the accessibility and affordability of hearing care for adults. One of their recommendations was for the Food and Drug Administration (FDA) to establish a category of OTC hearing devices for adults with mild or moderate hearing loss.[6] The President's Council of Advisors on Science and Technology has also recommended that FDA create a category of hearing aids for OTC available for adults with mild-to-moderate hearing loss in a manner similar to reading glasses.[7] In December 2016, FDA announced its commitment to consider creating a category of OTC hearing aids. FDA also issued a guidance document explaining that the agency does not intend to enforce the requirement that individuals 18 and up receive a medical evaluation or sign a waiver prior to purchasing most hearing aids.[8]

B. H.R. 1652, Over the Counter Hearing Aid Act of 2017

H.R. 1652 was introduced by Rep. Kennedy (D-MA), Rep. Carter (R-GA) and Rep. Blackburn (R-TN) on March 21, 2017. The bill establishes a definition for OTC hearing aids that covers units using the same scientific technology as traditional hearing aids, intended for use by

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[4] *See* note 2.

[5] *Id.*

[6] National Academies of Sciences, Engineering, and Medicine, *Hearing Health Care for Adults: Priorities for Improving Access and Affordability* (June 2, 2016) (http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults.aspx).

[7] The White House, *PCAST Recommends Changes to Promote Innovation in Hearing Technologies* (October 26, 2015) (https://obamawhitehouse.archives.gov/blog/2015/10/26/%E2%80%8Bpcast-recommends-changes-promote-innovation-hearing-technologies).

[8] Food and Drug Administration, *FDA takes steps to improve hearing aid accessibility* (Dec. 7, 2016) (https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm532005.htm).

adults with perceived mild to moderate hearing loss, and that allow the user to control and customize the unit for their perceived loss. No later than three years after enactment of the bill, HHS must propose regulations to establish a separate category for the regulation of OTC hearing aids. Final regulations shall be issued no later than 180 days after the close of the public comment period. These regulations should include requirements to provide reasonable assurances of safety and efficacy, to establish or adopt output limits appropriate for OTC hearing aids, for appropriate labeling of OTC hearing aids, and under which sale of OTC hearing aids is permitted. The bill prevents state or local governments from establishing any law that would restrict or interfere with the sale and use of OTC hearing aids. Finally, the bill directs HHS to finalize the draft guidance entitled "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products", which will clarify the products that meet the definition of a personal sound amplification product.

II. MEDICAL DEVICE ESTABLISHMENT INSPECTIONS

A. Background

FDA is responsible for inspecting medical devices and medical device establishments to ensure consumer safety. Under current law, registered medical device establishments of moderate or high risk devices are to be inspected every two years. It has been reported by medical device establishments that there are discrepancies in the inspection process, specifically between facilities located inside the United States and facilities located abroad. For example, some manufacturers have suggested that inspections in the United States can take significantly longer than inspections conducted outside the United States. Given that facility employees are expected to be engaged with the FDA investigator for the duration of the inspection, this can lead to disruption in daily workflow. Ultimately, according to the manufacturers, these discrepancies result in different inspection standards for facilities, despite belonging to a single company.

B. H.R. 1736, To amend the Federal Food, Drug, and Cosmetic Act to improve the process for inspections of device establishments and for granting export certifications

H.R. 1736 was introduced by Rep. Bucshon (R-IN), Rep. Brooks (R-IN), Rep. Peters (D-CA) and Rep. Butterfield (D-NC) on March 27, 2017. This bill aims to improve the process for FDA inspections of medical device establishments and for granting export certificates to foreign countries. Section two of the bill directs FDA to inspect device establishments using a risk-based inspection schedule. In establishing the risk-based schedule, HHS must consider previously established device risk factors and consider the participation of the device establishment in international device audit programs. In section three, FDA is directed to adopt a process and set of standards for inspecting device establishments. The process will include notification of the agent in charge of the establishment of the type and nature of the inspection, as well as announcing the inspection of the establishment within a reasonable time before inspection. For inspections other than for-cause inspections, FDA must provide a reasonable estimate of the timeframe for the inspection and maintain daily communications with the agent in charge of the establishment regarding inspection status. The bill also establishes a timeline to receive feedback from FDA once the inspection report has been received by the establishment. Not later than one

year after the date of enactment, HHS must issue draft guidance that specifies how FDA will implement the new inspection process, provides necessary templates for communication, develops a standard timeframe for inspection, and identifies practices for investigators. Final guidance must be issued no later than 18 months after the date of enactment.

With regards to foreign export certificates, FDA will provide a written justification for the denial of any export certificate and detail specific deficiencies leading to denial. FDA must also provide a process for review of a denied certification to allow establishments to address those deficiencies. HHS must issue guidance on the process within one year after enactment.

III. DIAGNOSTIC IMAGING EQUIPMENT FOR USE WITH CONTRAST AGENTS

A. Background

Contrast agents are substances which are used to enhance the contrast of structures or fluids within the body during medical imaging. They must be approved by FDA for use and their labeling requires correct dosing, rate and route of administration, and other items for safe use. Certain innovations in diagnostic imaging are complemented by the use of contrast agents. FDA has indicated that under current law the agency is unable to approve or clear an imaging device for use with a contrast agent where the use of the agent is not specified in the drug labeling. This would require contrast agents with a new indication to submit a supplement to CDER in order to update the labeling to reflect the new indication. For example, if a contrast agent was initially approved with a labeled indication for one part of the body for use with an imaging device, the contrast agent cannot be used for another part of the body (such as from hand to foot) unless the product has been approved and labeled for such use.

B. H.R. 2009, Fostering Innovation in Medical Imaging Act of 2017

H.R. 2009 was introduced by Rep. Costello (R-PA) and Rep. Peters (D-CA) on April 6, 2017. Under this legislation, FDA may approve a medical imaging device used with a contrast agent if the contrast agent a) has the same dose, rate and route of administration, b) affects the same region of the body, c) is used in the same patient population or population with similar risk, and d) has the same imaging modality as the previously approved contrast agent. As a part of this process, the Center for Devices and Radiological Health (CDRH) may consult with the Center for Drug Evaluation and Research (CDER), and may review information and data provided by the sponsor of a contrast agent. The bill also defines “applicable medical imaging device” and “contrast agent”. The bill also defines “new contrast indication” to mean the use of a contrast agent that is described in the approved labeling of an applicable medical imaging device.

IV. MEDICAL DEVICE THIRD PARTY SERVICE PROVIDERS

A. Background

Some medical devices will require servicing and maintenance over their lifecycle. This may include maintenance of x-ray equipment or repairing or replacing parts in a MRI system. Such servicing may be done by the original equipment manufacturer (OEM) or a third-party

service provider. OEMs are currently regulated by FDA and required to register, report adverse events, and comply with quality system regulations, among others. These same requirements do not currently apply to third party service providers. Stakeholders have expressed concerns that some third-party providers who service, repair, or maintain medical devices may be unqualified to perform these activities, or that the services performed may not be adequately documented. There has been some evidence of improper servicing that can result in disabled device safety features and improper or unexpected device operation. FDA recently held a public meeting in October 2016 to learn more about these concerns, the challenges facing third party service providers in performing service activities, and identify ways to mitigate risks associated with third-party servicing.

B. H.R. 2118, Medical Device Servicing and Accountability Act

H.R. 2118 was introduced by Rep. Costello (R-PA) and Rep. Peters (D-CA) on April 25, 2017. Under this legislation, establishments that service medical devices would be required to register with FDA, maintain a complaint handling system, and submit adverse event reports if they become aware of a death, serious injury, or malfunction associated with the servicing of the medical device.

V. WITNESSES

Panel I:

Jeffrey Shuren, M.D., J.D.
Director, Center for Devices and Radiological Health
Food and Drug Administration.

Panel II:

Thomas Powers, Ph.D.
Powers Consulting, LLC;

Frank Lin, M.D., Ph.D.
Associate Professor of Otolaryngology – Head & Neck Surgery, Geriatric Medicine, Mental Health, and Epidemiology
Johns Hopkins University;

Joe Robinson
Senior Vince President, Health Systems Solutions
Philips North America;

Robert Kerwin
General Counsel
International Association of Medical Equipment Remarketers & Servicers;

Patricia Shrader
Vice President, Global Regulatory Affairs
Medtronic